PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Warren, Keith S.
BARON & WARREN
19 South End, Kensington
London W8 5BU
GRANDE BRETAGNE

PCT

WRITTEN OPINION
(PCT Rule 66)

BY FAX IN ADVANCE

Date of mailing *(day/month/year)*	12.10.2004
Applicant's or agent's file reference: NGP0025-21	**REPLY DUE** within **2 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/04099	25.09.2003	25.09.2002

International Patent Classification (IPC) or both national classification and IPC
A61M5/32

Applicant
NMT GROUP PLC ET AL.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☒	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 25.01.2005

Name and mailing address of the international preliminary examining authority:
European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer
Sedy, R

Formalities officer (incl. extension of time limits)
Viegas da Cruz, I
Telephone No. +31 70 340-1923

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-16 as originally filed

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

   see separate sheet

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-18
Inventive step (IS)	Claims	1-18
Industrial applicability (IA)	Claims	

2. Citations and explanations

   see separate sheet

Re Item IV
Lack of unity of invention

1. This Authority agrees with the objection put forward by the Search Authority as to lack of unity, the reasons for the objection being as follows:

1.1 The present set of claims comprises three groups of claims which are not so linked as to form a single inventive concept:

Group I: Claims 1-3 and 11-18, when dependent on claim 1, are related to a syringe having a barrel, a plunger and a needle unit, the needle unit having a housing a needle-mounting hub, a biasing element, a stop element; the barrel having a seal (purpose: prevent leakage of syringe contents).

Group II: Claims 4, and 11-18, when dependent on claim 4, are related to a needle unit having a housing, a needle-mounting hub, a biasing element, a stop element blocking inward movement of the hub into the barrel, the stop element is arranged to snap between the needle hub and the housing (purpose: simple and effective manner of assembly of housing and hub).

Group III: Claims 5-10 are related to a needle unit having a housing, a needle-mounting hub, a biasing element, a stop element and a sheath (purpose: to shield the needle and to prevent premature release of the needle-mounting hub from the stop element).

1.2 The common concept linking together the independent claims of the above groups is the following: a needle unit having a housing, a needle-mounting hub, a biasing element, a stop element.

This common concept is not novel, see e.g. document US-B1-6228054 (document D1), column 8, lines 11-27, 51-56 and column 9, line 65 - column 10, line 25, Figures 2, 7-9, and item V below.

1.3 Since the remaining technical features specified in claims 1, 4 and 5, respectively, are not the same or corresponding technical features, a technical relationship between the subject-matter of the independent claims of the above indicated groups of claims

required by Rule 13 PCT does not exist, and the requirement for unity of invention is not fulfilled.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. First subject-matter, **claims 1-3, 11-18**

Document D1 discloses
a syringe (2) having a barrel, a plunger (1) and a needle unit (3), the needle unit having a housing connected to one end of the barrel;
a needle-mounting hub (11);
a biasing element (13) arranged to urge the hub (11) inwardly of the barrel;
and
a stop element (23) blocking inward movement of the hub (11) into the barrel until the hub (11) is released from the stop element (23) in response to the plunger reaching the final part of, or the conclusion of, its delivery stroke to allow retraction of the needle-mounting hub (11) so that a part for connecting the needle housing to the barrel is provided with a seal which contacts an outer peripheral surface of the stop element (23).

Consequently, claim 1 is not new in view of D1 so that the requirements of Article 33(2) PCT are not met.

2. Remark: The subject-matter of **claim 2** appears to be new and inventive. Consequently, the claim 2 together with dependent **claims 3, 11-18**, would meet the requirements of Article 33(2) and (3) PCT.

3. Second subject-matter, **claims 4, 11-18**
Claim 4 is not new in view of D1. Compare paragraph 1 of item V above.

4. **Claims 11-18**, when dependent on claim 4, do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see for example:

4.1 novelty
D1, figures 8, 9; column 9, line 65 - column 10, line 25, for claims 11,14-17;

4.2 inventive step
Claims 12, 13 and 18 define features which are merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed, namely secure holding between housing (14) and barrel (10)(regarding claims 12, 13) and easy way to insert stop element (15) into barrel (10)(regarding claim 18).

5. Claim 4 is not clear, contrary to Article 6 PCT, insofar as the wording "a biasing element arranged to urge the hub inwardly of the barrel" defines the needle unit by reference to a feature (barrel) which is not part of the claim (see Claim 4, line 1: "suitable for use with a syringe comprising a barrel..."). To clarify the claim "the barrel" has to be included into its scope.

5.1 Additionally, the claims 11-18, when dependent on claim 4, are not clear as far as they also refer to a barrel or a plunger which are not part of claim 4. Thus these claims do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined.

6. Third subject-matter, **claims 5-10**:

6.1 D1 discloses (see column 8, lines 11-27 and column 9, line 65 - column 10, line 25, Figures 2, 7-9)
a needle unit having the features as already listed in paragraph 1 of item V above.

The subject-matter of claim 5 differs from this state of the art in that a sheath is provided for enclosing the needle and a housing including one or more openings through which the sheath and stop element can make contact.

As such, claim 5 meets the requirements of Article 33(2) PCT.

The problem to be solved by this differing features is to shield the needle and to prevent premature release of the needle-mounting hub from the stop element.

It is not obvious to provide a sheath for enclosing a needle which can also make contact with a stop element insofar as extra openings for making the contact have to be provided in the needle housing.

Advantage: secure hold of stop element in the needle housing.

As such, the subject-matter of claim 5 also meets the requirements of Article 33(3) PCT.

Since claims 6-10 are dependent on claim 5 they also meet the requirements of Article 33(2) and (3) PCT.